REMARKS

The Office Action dated August 31, 2010, has been reviewed and the comments of the U.S. Patent and Trademark Office ("Office") have been considered. The following remarks are respectfully submitted to place the application in condition for allowance.

1. Status of Claims

Claims 1-25 are pending in this application. Claims 1, 3, 4, 6, 9-22, 24 and 25 are under examination, and claims 2, 5, 7, 8 and 23 are withdrawn by species election. Currently, Applicants submit amendments to claims 1, 12, 21 and 22, and cancel claims 14, 15, 24 and 25. Support for the claim amendments may be found throughout the disclosure, in particular, at page 4, lines 24-29, and page 22, line 20 through page 23, line 18. No new matter has been added by the claim amendments. Thus, Applicants respectfully request entry of the amended claims.

2. Claim Rejection under 35 USC § 112, second paragraph

The Office rejects claims 12 and 21 under 35 USC § 112, second paragraph, allegedly as being indefinite. Applicants submit that the amendments to claims 12 and 21, noted above, clarify the claims and render them definite. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

3. Claim Rejection under 35 USC § 101

The Office rejects claims 1, 3, 4, 6, 9-22, 24 and 25 under 35 USC § 101, allegedly as being directed to non-statutory subject matter. The Office asserted that the claims recite a series of mathematical steps for a diagnostic method that are not tied to a particular machine nor recite a physical transformation of matter. (Office Action at pages 3-4).

As indicated above, claims 14, 15, 24 and 25 are cancelled, thus rendering rejection of those claims moot. Further, Applicants have amended claims 1 and 22 to clarify the invention is directed to computer-based diagnostic methods. The claimed invention as amended requires a computer to perform the required steps, such as receiving and storing data, performing calculations and analysis, and outputting generated results. Thus, the claimed steps are tied to the computer and recite a physical transformation of the data to estimate the treatment response of a disease caused by the pathogen for claim 1, and to predict the clinical response to a drug of

a disease causing pathogen. Therefore, the claimed invention is directed to statutory subject matter, and Applicants request reconsideration and withdrawal of the rejection.

4. Claim Rejection under 35 USC § 102

The Office rejects claims 1, 3, 4, 9, 11, 14-20, 22, 24 and 25 under 35 USC § 102(b) as allegedly being anticipated by Harrigan *et al.* (*AIDS*, 2001; 15:1671-1677)("Harrigan").

As noted above, claims 14, 15, 24 and 25 are cancelled, thus rendering rejection of those claims moot. Further, Applicants respectfully disagree that the remaining claims are anticipated. Claim 1, as amended, is directed to a computer-based diagnostic method for estimating for a patient the treatment response of a disease caused by a pathogen to a drug, the method comprising: inputting data related to the genotype exhibited by a disease causing pathogen to a computer apparatus; determining by the computer apparatus the fold change resistance value of the pathogen infecting the patient; determining by the computer apparatus a clinical cut-off value which is the fold change resistance value at which a clinically relevant variation of clinical response is observed; wherein the clinical cut-off value is established by modeling the clinical response of a population of patients treated with the drug to the disease caused by the pathogen as a function of the fold change resistance of the pathogen infecting the patients; comparing, by the computer apparatus, the fold change resistance value of the pathogen infecting the patient to the clinical cut-off value; calculating, by the computer apparatus, the predicted treatment response of a disease caused by the pathogen, and outputting the results of the computer-generated estimate of the treatment response. Harrigan does not teach each of the elements of claim 1, nor of dependent claims 3, 4, 9, 11 and 16-20, and therefore, does not anticipate these claims.

Similarly, claim 22, as amended, is directed to a computer-based diagnostic system for predicting clinical response to a drug of a disease causing pathogen comprising: a) means for obtaining a genetic sequence of the disease producing pathogen; b) means for identifying at least one mutation in the genetic sequence of the disease producing pathogen; c) genotype database means comprising genotype entries; d) phenotype database means comprising phenotypes of patient fold change response values; e) clinical response database means comprising clinical response to drug treatment for reference sample patients; f) correlation means correlating a genotype entry with a phenotype, where the genotype entry corresponds with the obtained

genetic sequence of the disease producing pathogen; g) means for modelling clinical response to a drug of the disease causing pathogen by determining whether the patient fold change response is above a cut-off value, wherein the cut-off value is determined using the clinical response database means and comprises the fold change response value at which a clinically relevant diminished clinical response is observed; h) means for predicting the clinical response to a drug of a disease by determining whether the patient fold change response is above the cut-off value; and i) means for generating an output of the predicted clinical response to a drug of a disease causing pathogen. Harrigan does not teach each of these elements of the claimed method to anticipate.

Harrigan examines phenotypic variability in drug susceptibility in recombinant HIV-1 isolates from untreated HIV-positive subjects to establish *biologically relevant cut-off values* for phenotypic antiretroviral susceptibility testing. (Abstract; page 1672, second full paragraph)(emphasis added). Harrigan does not teach determining clinically relevant cut-off values. Specifically, Harrigan does not teach a computer-based diagnostic method of claim 1 for estimating for a patient the treatment response of a disease caused by a pathogen to a drug. Particularly, Harrigan does not teach the steps of determining a clinical cut-off value, inputting a request to a computer apparatus to compare the fold change resistance value of a pathogen infecting a patient to the clinical cut-off value; and outputting the results of the computer-generated calculations of the predicted treatment response of a disease caused by the pathogen. Furthermore, Harrigan does not teach the computer-based diagnostic system of claim 22 for predicting clinical response to a drug of a disease causing pathogen. In fact, Harrigan states "this study did not address clinical outcome." (Page 1676, second column, second paragraph). Therefore, Harrigan does not teach each and every element of the claimed invention to anticipate. M.P.E.P. § 2131; *W.L. Gore & Assocs. v. Garlock Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983); *Lindermann Maschinenfabrak GmbH v. American Hoist and Derek Co.*, 730 F.2d 1452, 1458, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). Accordingly, Applicants request reconsideration and withdrawal of the rejection.

5. Conclusion

Applicants submit concurrently a request for a one-month extension of time under 37 C.F.R. § 1.136 and the accompanying fee set forth in 37 C.F.R. §§ 1.17(a) paid by Credit Card

in the amount of $130.00. In the event that any additional extension of time is necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction with this submission (or with any paper filed by this firm for this application or resulting patent) to Deposit Account Number 50-2228, from which the undersigned is authorized to draw, under Order No. 026038.0265PTUS.

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Respectfully submitted,

By 

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